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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/171,916	02/16/1999	SMITA K. NAIR	1579-312	8645

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EXAMINER

GUZO, DAVID

ART UNIT PAPER NUMBER

1636

DATE MAILED: 05/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/171,916

Applicant(s)

NAIR ET AL.

Examiner

David Guzo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18, 25-27, 29-41 and 44-59 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 51 and 52 is/are allowed.
- 6) ☒ Claim(s) 1, 2, 6, 7, 9, 13-18, 27, 30, 41, 48, 49 and 53-58 is/are rejected.
- 7) ☒ Claim(s) 3-5, 8, 10-12, 25-26, 29, 31-40, 44-47, 50 and 59 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 October 1998 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### Detailed Action

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 2/3/04 has been entered.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 41 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 19 and 39 of copending Application No. 09/875,264 (hereafter the '264 application). Although the conflicting claims are not identical, they are not patentably distinct from each other because of reasons of record in the previous Office Action. It is noted that the claims

rejected have changed due to the cancellation of all but two claims (19 and 39) in the '264 application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicants traverse this rejection by asserting that since the provisional obviousness type double patenting rejection over claims in the '264 application is the only remaining rejection, it should be withdrawn and the case passed to issue.

Applicant's arguments filed 2/3/04 have been fully considered but they are not persuasive. Given the new grounds of rejection made in this Office Action, applicants arguments are not persuasive. Also, it is noted that, in the instant case, even if the instant provisional obviousness type double patenting rejection was the only remaining rejection, the rejection would be maintained. The '264 application is being prosecuted by a different examiner which has not made a double patenting rejection over the claims in the instant case. MPEP 804 recites that:

The "provisional" double patenting rejection should continue to be made by the examiner in each application as long as there are conflicting claims in more than one application unless that "provisional" double patenting rejection is the only rejection remaining in one of the applications. If the "provisional" double patenting rejection in one application is the only rejection remaining in that application, the examiner should then withdraw that rejection and permit the application to issue as a patent, thereby converting the "provisional" double patenting rejection in the other application(s) into a double patenting rejection at the time the one application issues as a patent.

In the present instance, since the examiner in the 09/875,264 application has not made a provisional double patenting rejection over the claims in the instant case, the circumstances recited in the MPEP are not operative because if the instant provisional

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double patenting rejection were withdrawn, both the instant case and the '264 application could issue without a terminal disclaimer being filed in either case. This would not be proper.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2, 6-7, 9, 13-18, 27, 28, 30, 48-49 and 53-58 are rejected under 35 U.S.C. 102(e) as being anticipated by Cezayirli et al.

Applicants claim a method for producing an RNA-loaded APC (i.e. a dendritic cell) that presents on its surface tumor antigen epitopes encoded by tumor derived RNA (which can comprise fractionated polyA+ RNA, nuclear RNA, nuclear RNA from breast or prostate cancer cells and wherein the RNA comprises a sequence that encodes a polypeptide (such as KDEL) which controls intracellular trafficking of a polypeptide to which it is attached) wherein the epitopes induce T cell proliferation, comprising introducing into an APC *in vitro* tumor derived RNA comprising tumor-specific RNA encoding an antigen that induces T cell proliferation and tumor immunity, thereby producing an RNA loaded APC. Applicants also claim APCs produced by the above method. Applicants also claim a method for treating tumors in a patient, comprising

administering the recited tumor RNA loaded APCs to said patient wherein the tumor RNA can be derived from the patient, fixed tissue or a donor patient. Applicants claim a method for producing a CTL which is cytotoxic for a cell presenting a tumor antigen, comprising providing a T lymphocyte, contacting the T lymphocyte with a tumor RNA-loaded APC and maintaining the T lymphocyte under conditions conducive to CTL proliferation. Applicants also claim a method for treating a tumor in a patient, comprising administering to patients CTLs obtained by incubating T lymphocytes with the aforementioned APCs.

Cezayirli et al. (US 6,228,640, issued 5/8/01, effective filing date 2/14/97, see whole document, particularly the Abstract, Fig. 1, column 4, lines 40-67; columns 5-8; column 10, lines 29-67-column 11, lines 1-37 and Claims 1-10) recites a method for producing a tumor cell RNA loaded dendritic APC wherein the tumor cell RNA can comprise polyA<sup>+</sup> RNA, total cell RNA, etc. from frozen tissues, fixed samples, the patient or a donor or from breast cancer or prostate cancer cells wherein the APCs express tumor cell antigens on the surface and wherein said epitopes induce T cell proliferation and tumor immunity. Cezayirli et al. also recite methods of treating cancer in patients comprising administering the RNA loaded APCs to patients or administering activated proliferated T lymphocytes (CTLs) obtained by incubating T lymphocytes with the RNA loaded APCs and a method for producing a CTL by incubating the RNA loaded APCs with T lymphocytes for a time sufficient to activate proliferation of the T lymphocytes to CTLs.

With regard to claims 48-49 reciting that the tumor cell RNA loaded into the APCs comprises a polypeptide which comprises an intracellular trafficking polypeptide (such as the well known KDEL polypeptide), it is noted that many polypeptides in any given cell have sequences which direct the intracellular transport of polypeptides to which they are attached and it must be assumed, absent evidence to the contrary, that the cellular RNA fractions used to create the RNA loaded APCs would contain numerous RNAs encoding such polypeptides. Cezayirli et al. therefore teaches the claimed invention.

Claims 51-52 are allowed.

Claims 3-5, 8, 10-12, 25-26, 29, 31-40, 44-47, 50 and 59 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

If a copy of a provisional application listed on the bottom portion of the accompanying Notice of References Cited (PTO-892) form is not included with this Office action and the PTO-892 has been annotated to indicate that the copy was not readily available, it is because the copy could not be readily obtained when the Office action was mailed. Should applicant desire a copy of such a provisional application, applicant should promptly request the copy from the Office of Public Records (OPR) in accordance with 37 CFR 1.14(a)(1)(iv), paying the required fee under 37 CFR

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1.19(b)(1). If a copy is ordered from OPR, the shortened statutory period for reply to this Office action will not be reset under MPEP § 710.06 unless applicant can demonstrate a substantial delay by the Office in fulfilling the order for the copy of the provisional application. Where the applicant has been notified on the PTO-892 that a copy of the provisional application is not readily available, the provision of MPEP § 707.05(a) that a copy of the cited reference will be automatically furnished without charge does not apply.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (571) 272-0767. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D., can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Guzo  
May 2, 2004

  
DAVID GUZO  
PRIMARY EXAMINER